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# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application for:

Steven K. Burke

Examiner: Schlientz, Leah H.

Serial No.: 10/686,808

Group Art Unit: 1618

Filing Date: October 16, 2003

For: **METHOD FOR PROMOTING BONE FORMATION**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313

## CERTIFICATE OF MAILING OR TRANSMISSION

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail on 11/7/06 in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Joyce D. Lange  
Typed or printed name of person signing certificate

## INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached Form PTO-1449 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application.

### I. Timing of the Information Disclosure Statement:

This Information Disclosure Statement is filed:

11/09/2006 TBESHAH1 00000015 10606000

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- ☐ With the new patent application submitted herewith (37 C.F.R. § 1.97(a)).
- ☐ Within three months after the filing date of the application or within three months after the date of entry of the national stage of a PCT application as set forth in 37 C.F.R. § 1.491.

- ☐ Before the mailing date of a first Office Action on the merits. In the event, however, that an Office Action has crossed in the mail with this Information Disclosure Statement, the Commissioner is hereby authorized to charge Deposit Account No. 07-1074 for any fees required pursuant to 37 C.F.R. §§ 1.17(p) or 1.17(i)(1).

This Information Disclosure Statement is filed:

- ☒ After the first Office Action and more than three months after the application's filing date; or PCT national stage date of entry filing but, as far as is known to the undersigned, prior to the mailing date of either a final rejection or a notice of allowance, whichever comes first, and the Commissioner is hereby authorized to charge Deposit Account No. 07-1074 for the fee (\$180.00) set forth in 37 C.F.R. § 1.17(p) and any additional required fees.

This Information Disclosure Statement is filed:

- ☐ After the mailing date of either a final rejection or a notice of allowance, whichever occurred first, and is accompanied by the fee (\$180.00) set forth in 37 C.F.R. § 1.17(i)(1) and a certification as specified in 37 C.F.R. § 1.97(e), as checked below. This document is to be considered as a petition requesting consideration of the Information Disclosure Statement.

The undersigned certifies that:

- ☐ Each item of information contained in the Information Disclosure Statement was first cited in any communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56 more than three months prior to the filing of this Information Disclosure Statement.

## **II. Copies of the Cited Items:**

- ☐ Copies of all of the items listed on the attached Form PTO-1449 are enclosed.
- ☐ Copies of only the following items listed on the attached Form PTO-1449 are not enclosed:

- ☐ Copies of those items in the attached Form PTO-1449 are not supplied because they were previously cited by or submitted to the Patent Office in a prior Application No. \_\_\_\_\_ filed \_\_\_\_\_ and relied upon in this application for an earlier filing date under 35 U.S.C. § 120. See 37 C.F.R. § 1.98(d).
- ☐ Copies of those items which are marked with an asterisk (\*\*) in the attached Form PTO-1449 were cited in a foreign examination report in a related case. A copy of the search report and the cited references not already of record in this application are attached hereto.

### **III. Concise Explanation of Relevance:**

Citation of the above documents shall not be construed as:


1. an admission that the documents are necessarily prior art with respect to the instant invention;
2. a representation that a search has been made, other than as described above; or
3. an admission that the information cited herein is, or is considered to be, material to patentability as defined in § 1.56(b).

It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached form PTO 1449 with initials or other appropriate marks.

The Commissioner is hereby authorized to charge Deposit Account No. **07-1074** for any additional fees required in connection with the filing of this Information Disclosure Statement.

Respectfully submitted,

November 7, 2006  
Date

By:   
Christopher M. Beck, PhD  
Attorney for Applicants  
Registration No. 52,603

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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(Use as many sheets as necessary)

Sheet

1

of

Application Number

**Complete if Known**

10/686.808

Filing Date

October 16, 2003

*First Named Inventor*

Steven K. Burke

*Art Unit*

1618

**Examiner Name**

Schlientz, Leah H.

Attorney Docket Number

438.1 US

## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

[illegible]

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449B/PTO

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STATEMENT BY APPLICANT**

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Sheet 2 of 2

**Complete if Known**

Application Number	10/686,808
Filing Date	October 16, 2003
First Named Inventor	Steven K. Burke
Art Unit	1618
Examiner Name	Schlientz, Leah H.
Attorney Docket Number	438.1

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		CHERTOW, G.M., BURKE, S.K., LAZARUS, J.M., STENZEL, K.H.L., WOMBOLT, D., GOLDBERG, D., BOVENTRE, J.V., AND SLATOPOLSKY, E., "Poly(allylamine hydrochloride) (RenaGel®): a noncalcemic phosphate binder for the treatment of hyperphosphatemia in chronic renal failure", Am. J. Kid. Dis. 29: 66-71 (1997)	
		GOLDBERG, D.I., DILLON, M.S., SLATOPOLSKY, E.A. GARRETT, B., GRAY, J.R., MARBURY, T., WEINBERG, M., WOMBOLT, D., AND BURKE, S.K., "Effect of RenaGel, a non-absorbed, calcium-and aluminum-free phosphate binder, on serum phosphorus, calcium, and intact parathyroid hormone in end-stage renal disease patients," Nephrol Dial Transplant 13: 2303-2310	
		CHERTOW, G.M., DILLON, M., BURKE, S.K. STEG, M., BLEYER, A.J. GARRETT, B.N., DOMOTO, D.T., WILKES, B.M., WOMBOLT, D.G., AND SLATOPOLSKY, E., "A randomized trial of sevelamer hydrochloride (RenaGel®) with and without supplemental calcium. Strategies for the control of hyperphosphatemia in hemodialysis patients," Clin Nephrol. 51: 18-26 (1999)	
		BLEYER, A.J., BURKE, S.K., DILLON, M., GARRETT, B., KANT, K.S., LYNCH, D., RAMAN, S.N. SHOENFELD, P., TEITELBAUM, I., ZIEG, S., AND SLATOPOLSKY, E., "A comparison of the calcium-free phosphate binder sevelamer hydrochloride with calcium acetate in the treatment of hyperphosphatemia in hemodialysis patients," Am.J. Kid Dis. 33: 694-701 (1999)	
		SLATOPOLSKY, E., BURKE, S.K., DILLON, M.A. AND THE RENAGEL STUDY GROUP, "RenaGel®, a nonabsorbed calcium and-aluminum-free phosphate binder, lowers serum phosphorus and parathyroid hormone," Kidney Int. 55: 299-307 (1999)	
		CHERTOW, G.M., BURKE, S.K., DILLON, M.A., AND SLATOPOLSKY, E. FOR THE RENAGEL STUDY GROUP, "Long-term effects of sevelamer hydrochloride on the calcium x phosphorus product and lipid profile of haemodialysis patients," Nephrol Dial. Transplant, 14: 2907-2914 (1999)	
		CHERTOW, G.M., BURKE, S.K., RAGGI, P., FOR THE TREAT TO GOAL WORKING GROUP, "Sevelamer attenuates the progression of coronary and aortic calcification in hemodialysis patients," Kidney Int. 62: 245-252 (2002)	
		Declaration of Melissa Plone under 37 C.F.R. §1.132	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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